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Docket No. 2003-003R1
PATENT

CERTIFICATE OF MAILING

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BY: Annie Wong

Annie Wong

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Carlson et al.

Serial No.: 10/790,956

Filed: March 1, 2004

For: Evaluating Effects of Exposure
Conditions on Drug Samples Over Time

Group Art Unit: 1639

Examiner: Unknown

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Transmitted herewith (check all that apply):

- | | |
|--|---|
| <input type="checkbox"/> Preliminary Amendment | <input checked="" type="checkbox"/> Information Disclosure Statement |
| <input type="checkbox"/> Response/Amendment | <input type="checkbox"/> Petition Under 37 CFR 1.97(d)(2) |
| <input type="checkbox"/> Response/Amendment After Final | <input type="checkbox"/> Formal Drawings |
| <input type="checkbox"/> Supplemental Amendment | <input type="checkbox"/> Declaration Under 37 CFR 1.131 |
| <input type="checkbox"/> Affidavits/Declarations | <input type="checkbox"/> Declaration Under 37 CFR 1.132 |
| <input type="checkbox"/> Declaration and Power of Attorney | <input type="checkbox"/> Terminal Disclaimer |
| <input type="checkbox"/> Supplemental Declaration | <input type="checkbox"/> Small Entity Statement |
| <input type="checkbox"/> Associate Power of Attorney | <input type="checkbox"/> Request for Refund |
| <input type="checkbox"/> Change of Correspondence Address | <input type="checkbox"/> Appeal |
| <input type="checkbox"/> Associate Power of Attorney | <input type="checkbox"/> Petition |
| <input type="checkbox"/> Response to Missing Parts | <input type="checkbox"/> Status Letter |

to be filed in the above-identified patent application.

☒ No fee is required.

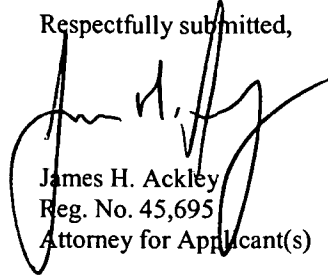
☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. § 1.16, in connection with the paper(s) transmitted herewith, or credit any overpayment of same, to Deposit Account No. 50-0496.

A duplicate copy of this Transmittal Letter is transmitted herewith.

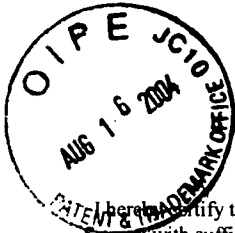
Date: 8-11-04

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Santa Clara, California 95051
Tel.: (408) 720-2598
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Respectfully submitted,

A handwritten signature in black ink, appearing to read 'James H. Ackley', is written over the typed name and title.

James H. Ackley
Reg. No. 45,695
Attorney for Applicant(s)



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PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Carlson et al.
Serial No.: 10/790,956
Filed: March 1, 2004
For: Evaluating Effects of Exposure
Conditions on Drug Samples Over Time

Confirmation No. 2161
Group Art Unit: 1639
Examiner: Unknown

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants submit herewith patents, publications and other information of which they are aware, which they believe an examiner may consider to be material to the patentability of the claims of this application, and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56.

While this Information Disclosure Statement may contain "material" information pursuant to 37 C.F.R. § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to herein is either "material" or "prior art" to the invention disclosed and claimed in the above-referenced application unless specifically designated as such. Applicants specifically reserve the right, where appropriate, to avoid or antedate any such reference by the appropriate arguments or showings under 37 C.F.R. § 1.131 and § 1.608, or any other appropriate means.

A completed PTO Form 1449 listing each reference is submitted herewith, and it is respectfully requested that an Examiner initialed copy of the PTO Form 1449 be returned to the undersigned. **Copies of each reference listed on the PTO Form 1449 are enclosed except for copies of the U.S. patent documents which are not supplied in accordance with the OG notice of August 5, 2003, partially waiving the requirements of 37 C.F.R. §1.98(a)(2)(i).**

This Information Disclosure Statement is being filed within three months of the filing or entry of the national stage of this application, or before the mailing of a first Office Action on the merits, whichever is later. No fee is required under 37 C.F.R. § 1.97(b). However, in the event that more than 90 days from filing have elapsed and a first Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the fee required under 37 C.F.R. 1.17(p) to Deposit Account Number 50-0496.

The Examiner is hereby requested to consider these references and other information and make them of record in the above-referenced application. Applicants respectfully submit that the claims of this application are patentable over the above-cited references and information. Examination and allowance of this application at an early date are requested.

Date: _____

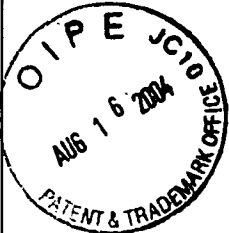
8-11-04

Respectfully submitted

By: _____

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INFORMATION DISCLOSURE CITATION  PTO-1449	ATTORNEY'S DOCKET NO.:	APPLICATION NO.:	
	2003-003R	10/790,956	
	APPLICANT: Carlson et al.		
FILING DATE: March 1, 2004		CONFIRMATION No.:	GROUP:
		2161	1639

US PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	5,948,438	9/07/99	Staniforth et al.	424	464	6/04/97
	6,004,617	12/21/99	Schultz et al.	427	8	6/07/95
	6,157,449	12/05/00	Hajduk	356	367	10/19/98
	6,312,917	11/06/01	Thakker et al.	435	25	12/04/98
	6,365,129	4/02/02	Fogarty	424	9.2	12/27/99
	6,371,640	4/16/02	Hajduk et al.	378	208	10/03/00
	6,423,351	7/23/02	Wang	424	648	3/09/01
	6,455,316	9/24/02	Turner et al.	436	37	4/13/00
	6,461,807	10/08/02	Friend et al.	435	4	11/10/00
	6,471,994	10/29/02	Staniforth et al.	424	489	8/27/99
	6,507,945	1/14/03	Rust et al.	717	103	5/05/99
	6,528,026	3/04/03	Hajduk et al.	422	198	11/19/98
	6,658,429	12/02/03	Dorsett, Jr.	707	104	1/05/01
	6,691,058	2/10/04	Blakley	702	130	4/29/02
	2001/0034067	10/25/01	Dales et al.	436	180	1/26/01
	2003-0116497	6/26/03	Carlson et al.	210	435	5/24/02
	2003-0118078	6/26/03	Carlson et al.	374	160	5/24/02
	2003-0119060	6/26/03	Desrosiers et al.	435	7.1	5/24/02
	2003-0124028	7/03/03	Carlson et al.	422	68.1	5/24/02

FOREIGN DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION Yes No	
	EP 1080435	2/27/02	EP	G06F	17/50		
	WO 96/11878	4/25/96	PCT	C01G	51/04		
	WO 98/40159	9/17/98	PCT	B01J	19/00		
	WO 99/59716	11/25/99	PCT	B01J	19/00	x	
	WO 00/23921	4/27/00	PCT	G06F	17/50		
	WO 00/36405	6/22/00	PCT	G01N	23/20		

FOREIGN DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION Yes No	
	WO 00/67086	11/09/00	PCT	G05B	19/414		
	WO 01/34290	5/17/01	PCT	B01J	19/00		
	WO 01/34291	5/17/01	PCT	B01J	19/00		
	WO 01/51919	7/19/01	PCT	G01N	30/00		

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages Etc.)

	Acc. Chem. Res., 29, 1996, pp. 1-170
/LA/	Aman et al., <i>Int'l Journal of Pharmaceutics</i> , 243, 2002, pp. 33-41
	<i>Chem. Rev.</i> , 97, 1997, pp. 349-509
	Borman, S., <i>Chem. Eng. News</i>, February 24, 1997, pp. 49-52 illegible copy
	Crowley et al., GlaxoSmithKline, <i>Pharmaceutical Technology Europe</i> , 2001
	Kerns et al., Wyeth Research, North Jersey ACS Symposium on Pharmaceutical Profiling, "Pharmaceutical Profiling Strategies for Drug Discovery", January 14, 2003
	Moyal et al., www.ncbi.nlm.nih.gov , "In Vivo Measurement of the Photostability of Sunscreen Products Using Diffuse Reflectance Spectroscopy"
	Serajuddin et al., <i>Journal of Pharmaceutical Sciences</i> , 88, July 1999, pp. 696-704
	Terret, N., <i>Drug Discovery Today</i> , 1, 1996, 402
	Thayer, A.M., <i>Chem. Eng. News</i> , February 12, 1996, pp. 57-64
	Trivedi, J. and Wells, M. (authors), Rong, Lui (editor), "Solubilization Using CoSolvent Approach", <i>Water-Insoluble Drug Formulation</i> , Chapter 7 Interpharm Press, 2000, pp. 141-168
	"Stability Considerations in Dispensing Practice", United States Pharmacopeia, 25, 2002, pp. 2231-2234
	www.fda.gov , Drug Stability Guidelines, Section 1 – General Considerations
	www.integratedservices.com , Sanyo Pharma Safe System
	www.q-panel.com , Q-Sun Xenon Test Chambers
	U.S. Patent Application No. 09/174,856, filed October 19, 1998
	U.S. Patent Application No. 09/420,934, filed October 19, 1999
	U.S. Patent Application No. 09/550,549, filed April 14, 2000
	a copy with this serial number has not been provided
EXAMINER:	/Lyle Alexander/
DATE CONSIDERED:	06/17/2008

Examiner: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /LA/